REMARKS

I. Preliminary Remarks

As stated above, the present response is timely filed as it is accompanied by a petition of time to file in the third month along with the requisite fee. While the applicants believe that no additional fees are due for consideration of this response, should the Patent Office deem further fees necessary, authorization is hereby granted to charge such additional fees to Deposit Account No. 13-2855. Any refunds due should be forwarded to the undersigned's law at the address listed below.

The applicants have noted the examiner's assertion of double-patenting on pages 2-4 of the official action. Without agreeing with the examiner's allegations, the applicants will forward, under separate cover, a duly executed terminal disclaimer.

With respect to the objections to the specification (sequence compliance, corrections to priority, and descriptions of the drawings), the applicants will forward any amendments in a supplemental response.

II. Rejections Based Upon 35 U.S.C. §112, First Paragraph

The Rejection of Claims 1-15 and 29-32 under 35 U.S.C. 112, first paragraph Should Be Withdrawn

In Paragraph 6 of the outstanding official action, the examiner rejected claims 71-114 under 35 U.S.C. §112, first paragraph, alleging that the specification while enabled for a composition comprising an effective amount of human stem cell factor polypeptide and one or more cytokines, wherein the SCF composition enhances hematopoieses, the specification does not (allegedly) enable,

(a) biologically active fragments or analogs of SCF, wherein the treatment is effective to treat hematopoietic disorders, epithelial cell disorders, stromal cell disorders, neural disorders, pigmentation disorders, and germ cell disorders;

(b) SCF polypeptides consiting of amino acid sequences 1-100, 1-110, 1-120, 1-123, 1-127, 1-133, 1-141, 1-145, 1-148, 1-152, 1-156, 1-157, 1-158, 1-159, 1-160, 1-161, 1-163, 1-166, 1-168, 1-173, 1-178, 1-180,

1-183, 1-185, 1-188, and 1-189 as st forth inFig. 42A-C and Fig 44A-C;

(c) all analogs and variants of the disclosed SCF polypeptide (*e.g.*, 1-100, 1-110, 1-120, 1-123, 1-127, 1-133, 1-141, 1-145, 1-148, 1-152, 1-156, 1-157, 1-158, 1-159, 1-160, 1-161, 1-163, 1-166, 1-168, 1-173, 1-178, 1-180, 1-183, 1-185, 1-188, and 1-189 of Seq ID Nos 46, 61 and 63;

(d) polynucleotides that encode polypeptides that are "at least 70 percent identical to the polypeptide of SEQ ID NO:2 or SEQ ID NO:4."

In support of her position, the examiner stated that

> [d]ue to the large quantity of experimentation necessary to generate the biologically active derivatives or analogs recited in the claims, to determine the specific activity of a polypeptide fragment and to determine the efficacy of treatment, the lack of direction/guidance presented in the specification regarding which structural features that are required in order to provide activity, the absence of working examples directed to the same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the effects of mutation on protein structure and funcation, and the breadth of the claims which fail ti recite any structural or functional limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

In Paragraph 7 of the official action the examiner rejected claims 71-114 as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The examiner alleged that the specification does not specifically point out our discuss huma SCF fragments comprising amino acids 1-100, 1-110, 1-120, 1-123, 1-127, 1-133, 1-141, 1-145, 1-148, 1-152, 1-156, 1-157, 1-158, 1-159, 1-160, 1-161, 1-163, 1-166, 1-168, 1-173, 1-178, 1-180, 1-183, 1-185, 1-188, and 1-189 of SEQ ID Nos 46, 61, and 63.

The applicants respectfully traverse this rejection and submit that the claims, as originally filed, are fully enabled by specification. Specifically, the applicants assert that one of skill in the art , in view of the teachings of the specification, and in view of the state-of-the-art at the time the present application was filed, would be able to practice the invention encompassed by these claims without undue experimentation.

In order to satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph, the specification must teach one of skill in the art to make and use the invention without undue experimentation. Atlas Powder Co. V. E.I. DuPont de Nemours, 750 F.2d 1569, 224 USPQ 409 (1984). This requirement is satisfied by providing sufficient disclosure, either through illustrative examples or terminology, to teach one of skill in the art how to make and how to use the claimed subject matter without undue experimentation. This clause does not require "a specific example of everything within the scope of a broad claim." In re Anderson, 176 USPQ 331, at 333 (CCPA 1973). Furthermore, the amount of experimentation that is permissible depends upon a number of factors, which include the quantity of experimentation necessary, the amount of direction or guidance presented, the state of the prior art, the relative skill of those in the art, the predictability of the art and the breadth of the claims. Ex parte Forman, 230 USPQ 546 (Bd. Pat. App. And Int'f (1986); *see also* In re Wands, 8 USPQ2d 1400 (Fed. Cir. (1988)).

In view of the law, the applicants assert that they have satisfied the enablement requirement by providing sufficient disclosure to teach one of skill in the art how to make and use the claimed invention. The applicants have clearly defined their invention both in terms of structure and function. With respect to structure, the examiner has admitted that the specification teaches a SCF polypeptide and fragments thereof. Regarding function, the applicants submit that the disclosed SCF polypeptides have been defined by their expression and their association/use in many disease states. Specifically, the present application discloses many situations in which treatment with SCF polypeptides and/or biologically active fragments would be useful to treat and underlying disease state (see pages 17-31 of the specification).

Given the amount of guidance presented in the specification and the high level of (court-recognized) skill in the biotechnological art, one of skill in the art would readily and easily be able to make and use the biologically active variants, analogs and fragments of SCF polypeptides without undue experimentation. Specifically, the specification discloses that biologically active variants, analogs and fragments of SCF polypeptides, wherein one or more nucleotides and/or amino acids are designed to differ from the wild-type or naturally occurring SCF, can be produced using techniques that are well known in the art.

The applicants also assert that, in view of the foregoing comments and in view of the specification, the claims are sufficiently enabled for "biologically active" analogs and

fragments. Such a description is more than sufficient to support a claim to a limited genus *i.e.* biologically active variants analogs and fragments, as in the instant case.

Furthermore, there is no requirement in patent law that every species within a 'genus' claim be disclosed. Specifically, "[i]t is manifestly impracticable for an applicant who discloses a generic invention to give an example of every species falling within it, or even to name every such species, it is sufficient if the disclosure teaches those skilled in the art what the invention is and how to practice it." In re Grimme, Keil and Schmitz, 124 USPQ 499,502 (CCPA 1960). Thus, the applicants are entitled to claims that are not only commensurate in scope with what they have specifically exemplified, but also commensurate in scope with that which one of skill in the art could obtain by virtue of that which the applicants have disclosed.

Finally, it would be unfair, unduly limiting and contrary to the public policy upon which U.S. patent law is predicated to limit the claims to nucleic acid molecules and polypeptides by naturally-occurring sequences of nucleotides and polypeptides encoded by them. To do so would permit those of skill in the art to use the disclosure of the instant application, but avoid infringing such limited claims merely by making routine amino-acid substitution, deletions or alterations to generate biologically active fragments or analogs of SCF polypeptides..

In view of the foregoing comments and the amendments to the claims herein, the applicants submit that claims 71-114 are fully enable by the present specification and therefore respectfully request that the rejection of the claims under 35 U.S.C. §112, first paragraph be withdrawn.

II. The Rejections Based Upon 35 U.S.C. §112, Second Paragraph Should be Withdrawn

Claims 71-114 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter that the applicants regard as their invention.

Specifically and with respect to claims 71-114, the examiner alleged that the phrase "thereof" renders the claim indefinite because it is unclear whether "thereof" refers to the entire polypeptide or variants and fragments of the SCF polypeptide. With respect to the use if abbreviations for the various cytokines, the examiner stated that use of such abbreviations

renders the claims vague and indefinite.

In response, the applicants respectfully traverse this rejection and submit that the claims are not indefinite. More specifically, the applicants respectfully point out that the phrase "thereof" clearly refers to claim fragments and analogs of the SCF polypeptide. The applicants submit that one of skill in the art would readily understand this phrase. With respect to use of cytokine abbreviations, the applicants note that such abbreviations are art-recognized abbreviations and as such are neither vague nor indefinite.

In view of the foregoing comments and the amendments to the claims herein, the applicants submit that claims 71-114 are not indefinite and do particularly point out and distinctly claim the subject matter that the applicants regard as their invention. and therefore respectfully request that the rejection of the claims under 35 U.S.C. §112, second paragraph be withdrawn.

III. Conclusion

In view of the foregoing comments and amendments, the applicants submit that the claims are in a condition for allowance and early notification thereof is respectfully requested. Should the examiner wish to discuss any aspect of the present application, she is urged to contact the undersigned at the telephone number indicated.

Respectfully submitted,

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